More specifically, the Examiner stated that the claimed alleviation of HIV infection in a human infected with HIV by administration of NaCl appears to have specific and substantial utility.

However, the Examiner indicated that the specification does not appear to show any working examples, but appears to provide only hypothetical statements of what would occur. Furthermore, the Examiner commented that applicant has not shown by what mechanism, theoretical or otherwise, that administration of NaCl results in reduction of HIV infection.

Applicant respectfully reiterates, as stated in the Response to the first Official Action, that the U.S. Patent Laws contain no requirement for actual working examples, and that therefore, prophetic examples are acceptable. The reason is that the filing of an application constitutes a constructive reduction to practice of the invention. See, *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984).

Nor is it a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. See, *In Re Cortright*, 49 U.S.P.Q.2d 1464, 165 F.3d 1353 (Fed. Cir. 1999).

Moreover, applicant respectfully points out that such comments by the Examiner vis-à-vis lack of working examples are an enablement issue under 35 U.S.C. §112, first paragraph, not a credible utility issue under 35 U.S.C. §101. See, both *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., supra, and In Re Cortright, supra.*

Enablement under 35 U.S.C. §112, first paragraph, was discussed in the Response to the first Official Action.

In connection with enablement, applicant respectfully reiterates that his specification and prophetic examples teach in great detail how to make and to use applicant's invention, namely administration of NaCl to a HIV infected person in order to achieve alleviation of the HIV infection. More specifically, the gist of the present invention is to administer a NaCl formulation to a HIV infected person where the amount of NaCl is more than the person's average daily intake, but is less than the toxic amount which would kill the person. Administration of this amount of NaCl to the person is periodically repeated to achieve alleviation of the HIV infection. Hence, applicant's specification and prophetic examples are clearly sufficient to teach the person of ordinary skill in the art how to make and to use the invention, without undue experimentation.

As stated in the Response to the first Official Action, although applicant does not intend to be bound to any theory, applicant believes the following describes the mechanism of his invention.

Applicant theorizes that the mechanism is that the administration of extra NaCl beyond the average daily intake will be enough to disrupt the HIV virus cells, which are relatively small in size as compared to the size of human cells, but not enough (i.e., less than the toxic amount of NaCl) to disrupt the relatively larger human cells. Because of the relatively small size of the HIV virus cells, they should be ruptured by a change in osmotic pressure resulting from dehydration of the viral cells by extra NaCl in an amount that is more than the average daily intake, but that is still less than the amount needed for rupturing the larger human body cells by a change in osmotic pressure resulting in dehydration. In other words, the amount for rupturing human cells is the toxic amount as measured by TCLo or as measured by LD50, and the extra NaCl always is to be kept less than this toxic amount.

The size difference between the relatively small HIV virus cells and the relatively large human cells is well known to those of ordinary skill in the art of medicine, immunology, and the like.

Applicant again points the Examiner's attention to the brochure enclosed with the Response to the first Official Action to assist the Examiner in understanding the size difference, namely the Merck brochure entitled "Livin'It" describing their drug CRIXIVAN® for treatment of HIV infection. The first two pages of this brochure have a drawing that shows the small HIV virus cell in red attached to the large human cell in blue.

As discussed in more detail below in connection with credible utility under §101, applicant notes this Merck brochure also contains a discussion of the mechanism of how a HIV infection occurs. The HIV infection occurs by the small HIV virus cell attaching itself to the large human CD4 T-cell and then using the DNA of the human CD4 T-cell to replicate. The HIV virus cell has viral RNA, but does not have DNA, and thus cannot replicate on its own.

Further in connection with the rejection under 35 U.S.C. §101, the Examiner stated in the Final Rejection that:

> Applicant indicates that the administration should result in circulating levels of NaCl within the range of about 0.05 μM to about 1.0 μM and that the extra amount of NaCl will disrupt the HIV virus. [However,] In Hrinda et al. (US Pat. 5,661,023) it is disclosed that NaCl concentrations as high as 1.4 M for prolonged

> periods, such as greater than 18 hours, only resulted in partial disassembling of HIV particles with dilution to 0.25 M being sufficient to prevent the same (Hrinda et al., Column 8, lines 51 - 68, Column 9, lines 1 - 12). Thus, it appears that the effective amount of NaCl need to disrupt the HIV virus far exceeds what is disclosed and claimed as being the effective therapeutic range as well as the level of NaCl which would be considered to be safe in humans.

Applicant respectfully submits that the Examiner has completely misconstrued Hrinda et al. in connection with the present invention.

More specifically, Hrinda et al. disclose an elution process for obtaining HIV particles. In the process, the HIV particles are inactivated by beta-propriolactone (BPL) for about 18 – 24 hours. The BPL-treated HIV particles are then concentrated by flowing them through a membrane, followed by buffering them with phosphate buffered saline (PBS). The PBS solution with the HIV particles is then passed through columns containing an anion exchange resin, such as TMAE FRACTOGEL®.

The HIV particles attach to the TMAE FRACTOGEL® resin, and are subsequently washed with a NaCl solution containing 0.1 – 0.55 M NaCl, buffered at a pH of 6 – 7.5. Then the attached HIV particles are eluted off the resin using a higher NaCl concentration at 0.6 - 2 M, preferably 0.8 - 1.4 M, at the same buffered pH of 6 - 7.5. The eluted solution containing the retroviral particles, particularly HIV, is diluted to reduce the NaCl concentration to within the range of 0.05 - 0.25 M to prevent the partial disassembling of the HIV-1 particles when exposed to the eluant's high NaCl concentration for prolonged periods of time, such as greater than 18 hours.

In short, in Hrinda et al., the NaCl concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours, in order avoid partially disassembling HIV particles, are concentrations for HIV particles floating in phosphate buffered aqueous NaCl.

In contrast, applicant's desirable circulating levels of NaCl being within the range of about 0.05 μM to about 1.0 μM are concentrations in human blood in a human body for HIV particles attached to human CD4 T-cells, not for HIV particles floating in phosphate buffered aqueous NaCl. *See*, the Merck brochure entitled "Livin'It" for a discussion of the mechanism of how a HIV infection occurs by the small HIV virus cell attaching itself to the large human CD4 T-cell and then using the DNA of the human CD4 T-cell to replicate since the HIV virus cell has viral RNA, but does not have DNA, and thus cannot replicate on its own.

Therefore, applicant respectfully submits that the person of ordinary skill in the art would thus expect the claimed invention to function in the disclosed manner based upon current scientific understanding because that person would be aware of the mechanism for HIV infection, as illustrated in the Merck brochure, and as a result, that person would not expect HIV particles attached to human CD4 T-cells to behave like HIV particles floating in phosphate buffered aqueous NaCl. Rather, that person would expect applicant's claimed invention to function as a treatment for HIV infection in a human. *See,* Utility Examination Guidelines, published at 66 FR 1092 (January 5, 2001), 1242 O.G. 162 (January 30, 2001).

Accordingly, applicant respectfully requests the Examiner to withdraw the rejections of claims 22 - 42 under §101.

In summary vis-à-vis credible utility under 35 U.S.C. §101 and enablement under 35 U.S.C. §112, first paragraph, applicant respectfully submits the following discussion of *In Re Cortright, supra.*

Cortright's patent involved rubbing Bag Balm®, the active agent of which is 8-hydorxy-quinoline sulfate, into the scalp to treat baldness.

More particularly, Cortright's claim 15 set out as claim requirements her **surmised theory** of the mechanism for how her invention worked, namely offsetting the effects of lower levels of a male hormone being supplied by arteries to the papilla of scalp hair follicles with the active agent 8-hydorxy-quinoline sulfate to cause hair to grow again on the scalp, comprising rubbing into the scalp the ointment having the active agent 8-hydroxy-quinoline sulfate 0.3 % carried in a petrolatum and lanolin base so that the active agent reaches the papilla.

The Court of Appeals specifically stated that it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. Thus, Cortright was not required to prove the cause of the hair growth, and claim 15 was not invalid for lack of utility under 35 U.S.C. §101.

However, there was no laboratory data showing that the effects of lower male hormone levels have been offset by Bag Balm® nor even if Bag Balm® has reached the papilla, as required by the language in claim 15. Thus, claim 15 was invalid for not satisfying the how to use requirement of 35 U.S.C. §112, first paragraph.

In contrast, the present applicant's claims do **not** set out as claim requirements applicant's **surmised theory** of how his invention works by the NaCl disrupting the relatively small HIV virus cell.

Next, with regard to the Examiner's rejection of claim 35 under §112, first paragraph, applicant respectfully points out the following.

The Examiner stated that his reason for the rejection was that the specification does not provide enablement for transdermal administration, and the Examiner cited the journal article entitled "Salt Water Soaking Possible Alternative Psoriasis Treatment" from *Dermatology Times*, which contains a statement that there was no transdermal uptake of NaCl from a *salt bath*.

Applicant notes that the Examiner is correct with respect to what the journal article states, but applicant respectfully submits that the Examiner appears not to understand transdermal administration.

No transdermal uptake of NaCl from a salt bath is what is expected because soaking in the salt bath only provides for *topical administration* of NaCl.

In contrast, transdermal administration is effected with a skin patch containing various chemicals, in addition to the agent that it is desired to administer transdermally. Applicant clearly provided enablement by the reference on lines 13 – 15 of page 5 of his specification vis-a-vis an explanation of transdermal administration via a skin patch being in U.S. Patent No. 5,016,652 to Rose and Jarvik.

Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of claim 35 under the first paragraph of §112.

CONCLUSIONS

By the above Remarks, applicant respectfully submits that the present invention as now claimed is enabled by the specification in such a way as to convey to the person of ordinary skill in the art that applicant had possession of the claimed invention and in such a way as to teach a person of ordinary skill in the art to make and/or to use the invention without undue experimentation. The filing of the application with prophetic laboratory examples is a constructive reduction to practice. Accordingly, applicant respectfully requests the Examiner to withdraw his comments vis-à-vis the lack of working examples.

Moreover, in view of the above Remarks, applicant respectfully submits that the invention as claimed has credible utility, as there is no requirement that an inventor set forth, or know how or why the invention works, and thus, the Examiner is respectfully requested to withdraw the rejection of claims 22- 44 under §101.

Also, in view of the above Remarks, applicant respectfully submits that transdermal administration is clearly enabled, and thus, the Examiner is respectfully requested to withdraw the rejection of claim 35 under the first paragraph of §112.

Applicant respectfully submits that the present application is in proper condition for allowance and respectfully solicits official notification of allowance from the Examiner.

If a minor issue remains outstanding after the Examiner has studied the above Remarks, the Examiner is respectfully requested to telephone the undersigned attorney so that any such matter may be resolved and the application be placed in condition for allowance without the necessity for continuing with the Appeal.

DEPOSIT ACCOUNT

Although a check in the amount of $625.00 is enclosed ($465.00 for the extension of time fee + $160.00 for the Notice of Appeal fee) and it is believed that no further fee is due, the Commissioner is hereby authorized to charge any deficiencies of payment associated with this Communication, or to credit any overpayment, to Deposit Account No. 13-4365.

Respectfully submitted,

Moore & Van Allen PLLC

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JLS/lsg
Enclosures:
Petition for 3-Months Extension of Time
Notice of Appeal
Check in the amount of $625.00 ($465 for 3-month extension + $160 for Notice of Appeal)

In re application of:	Bass, Ralph L.	Docket Number:	014123-000008
Application Number:	09/721,131	Art Unit:	1616
Filed:	November 22, 2000	Examiner:	Frank Choi
For:	Method for Treating HIV		

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